## **Applying Axiomatic Design Methodology for Guideline Revision**

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We are investigating the use of axiomatic design (AD) as a principled approach to the revision of guidelines. AD models guidelines in a modular and hierarchical manner and captures interactions between modules. To test this approach we applied AD to encode segments of three guidelines and their revised versions. Guideline encodings for the original versions were modified to incorporate changes made in the revised documents. The results indicate that AD is a promising approach for guideline modeling.

One limitation common to guideline-knowledge representation approaches is that revision of guidelines or adaptation of guidelines to local clinical contexts is not supported. Guideline modifications of this type place the following desiderata on the representation schema and authoring tools: 1) changes to one part of the guideline should have minimal impact on other parts; 2) the authoring tools should direct the user to review those parts of the guideline impacted as a result of changes elsewhere in the guideline; and 3) the tools must assist with integration of revised guidelines into the locally-adapted guidelines.

We are investigating axiomatic design (AD) [1] as a principled methodology for guideline modeling. The result of applying AD is a modular design with a hierarchical structure. Successively lower-level modules of the hierarchy represent increasing details of the design. For example, a design for a cancer treatment protocol might contain a chemotherapy module at a high level and modules for drug administration and for toxicity monitoring at a lower level. We hypothesize that guidelines specified as hierarchical modules would allow for easier local modification and revisions. Furthermore, AD also identifies interaction (dependencies) among modules at the same level of the hierarchy using a design matrix. Thus, if a change on one module (e.g., drug administration schedule) has an impact on other modules (e.g., toxicity monitoring), the affected modules can be readily identified and modified.

We applied this method to encode segments of three national guidelines released during 2000-2001 and subsequently revised in 2002-2003: Lipid Screening (LS) in Adults, Hormone Replacement Therapy (HRT), and Initiation of Antiretroviral Therapy (HIVRX). We assessed the number of modules used in the design, the interaction among modules, and the types of revisions made.

The AD of the original LS guideline had 10 modules in a four-level hierarchy with interaction among modules at levels 2 and 3 from the top. Revision of this guideline included a change in the test used for screening and in the threshold values of the test results used for starting treatment. The revision required removal of a module at level 3 and both its children at level 4. This *primary* change impacted another module at the same level and that module was also removed. The resulting guideline contained 6 modules at 3 levels and had interactions among modules at level 2.

The original HRT guideline was encoded in a 7 module 4-level design and did not have interactions at any levels. The guideline was revised to exclude heart disease as a possible indication for HRT. Changes in the details of one module at level 3 led to the removal of its two children. These changes had no impact on other modules because there were no interactions. The resulting design had 5 modules, 3 levels, and had no interactions.

The original HIVRX guideline had 6 modules in a 3 level, with interactions at level 3. The guideline was revised to replace an earlier version of the bDNA test with a more accurate version now interchangeable with the RT-PCR test. This required a localized change in a module on level 3. This change impacted another module on the same level. That module was inspected but did not require changes.

Changes were generally made at the lower levels of the hierarchy preserving upper-level intentions. The modules produced either had no interactions or had unidirectional interactions (i.e., the dependency was one-way only) and could therefore be changed with minimal effect on each other. In the case of interactions, the design matrices clearly demonstrated the impact of a primary change on other modules. AD appears useful for revising guidelines. We will continue to explore its use for guideline revision and adaptation to local contexts.

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## References

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